REMARKS

Claims

Upon entry of this Amendment, claims 1, 5, 6, 10, 11, 29-31, 38-41, 44, 46 and 47 will be pending in the application with claims 1 and 44 being independent. Claims 2-4, 7-9, 12-28, 32-37, 42, 43, 45, 48 and 49 are canceled. Claims 1, 44, 46 and 47 are currently amended. No claims have been added. Reconsideration is respectfully requested.

Interview Summary

Applicants wish to thank the Examiner for the courtesy extended to them in the Interview with their representative Trent K. English on July 8, 2009. During the Interview, claims 1 and 44-47 were discussed, as well as the prior art references to Manthrop et al. and Bremer. No conclusion was reached, but Mr. English and Examiner Philogene agreed that amendments to the claims regarding the implant delivery device may place the application in condition for allowance. Accordingly, Applicants have amended the claims for reconsideration by the Examiner.

Claim Rejections – 35 U.S.C. §103(a)

Claims 1, 6, 10, 11, 29-31, 38-41, 44, 48, and 49 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Manthrop et al. (U.S. Patent No. 5,916,217) in view of Bremer (U.S. Patent No. 5,549,620). Claim 5 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Manthrop et al. in view of Bremer and in further view of Hair (U.S. Patent No. 6,197,037). Claims 10 and 11 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Manthrop et al. in view of Bremer and in further view of Hair and in further view of Pohndorf et al. (U.S. Patent No. 5,904,683). Claims 45-47 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Manthrop et al. in view of Bremer and in further view of Cullen (U.S. Patent No. 2,065,659). Applicants have amended independent claims 1 and 44 to now recite

limitations associated with an implant delivery device including selected features recited in claim 45. Accordingly, Applicants respectfully traverse the rejection to dependent claim 45. Applicants believe the application is now in condition for allowance. Numerals used below are merely exemplary and are not intended to limit the scope of the claims in any way.

Claim 1 recites a system comprising a self-retaining implant 10 for attaching a bone cover 130 or a bone fragment 130 to a skull 140 and an implant delivery device 40 for driving the implant into the bone cover 130 or bone fragment 130. The implant 10 comprises a support element 12 having an upper side 18 and a lower side 20. An extension 14 extends substantially at a right angle from the lower side 20 of the support element 12 to an end remote from the support element 12 and substantially straight between the support element 12 and the end. At least one spike 16 extends substantially parallel to the support element 12 such that the spike 16 can be driven laterally into the bone cover 130 or bone fragment 130 prior to positioning the bone cover 130 or bone fragment 130 adjacent to the skull 140. The support element 12 further comprises two support arms 22, 24 extending in opposite directions from the extension with the first 22 of the two support arms defining a screw hole 26 therein for receiving a fastener 150 to secure the first support arm 22 to the skull 140 after the spike 16 has been driven laterally into the bone cover 130 or bone fragment 130 and after positioning the bone cover 130 or bone fragment 130 adjacent to the skull 140. The second 24 of the two support arms cooperates with the bone cover 130 or bone fragment 130 when driving the spike 16 into the bone cover 130 or bone fragment 130.

The implant delivery device 40 comprises a body 42 and a receiving element 46 supported by the body 42. The receiving element 46 defines a receiving structure at one end thereof for receiving the implant 10. A driving-in mechanism 40 is operative with the receiving element for driving the at least one spike 16 of the implant 10 laterally into the bone cover 130 or bone fragment 130. An operating mechanism 54 is coupled to the body 42 to actuate the driving-in mechanism 40 and drive the at least one spike

16 laterally into the bone cover 130 or bone fragment 130.

Claim 44 now recites a method of attaching the bone cover 130 or bone fragment 130 to the skull 140 with the implant 10 using the implant delivery device 40. The method includes positioning the implant 10 in the receiving structure of the receiving element 46, actuating the driving-in mechanism 40 and driving the spike laterally into the bone cover 130 or bone fragment 130 prior to positioning the bone cover 130 or bone fragment 130 adjacent to the skull 140 and securing the first support arm to the skull 140.

Manthrop et al. discloses an implant 110 for attaching a bone flap 16 to a skull 22. Referring to Figure 3, the implant 110 of Manthrop et al. comprises a support element having a flap clipping portion 112 and a skull clipping portion 118. An extension 124 extends downwardly from a lower side of the support element to a remote end. A pair of burrs 132 extends at an acute angle from the extension 124. In practice, multiple implants 110 are used to attach the bone flap 16 to the skull 22. In this process, each of the implants 110 of Manthrop et al. are first attached to the bone flap 16. To accomplish this, a screw 140 is secured to the bone flap 16 through a screw hole defined in the flap clipping portion 112. When the implants 110 are secured to the bone flap 16, the burrs 132 protrude outwardly from the bone flap 16. Then, with the implants 110 secured to the bone flap 16, the bone flap 16 is pressed into an opening in the skull 22. The burrs 132 flex inwardly as the bone flap 16 is positioned in the opening. Once in position in the opening, the normal biasing force of the burrs 132 urges the burrs 132 outwardly to penetrate into the skull 22 to hold the bone flap 16 in position. Manthrop et al. does not use an implant delivery device to drive the burrs laterally into a bone cover or bone fragment, as required by claims 1 and 44. To start, the burrs 132 of the implant in Manthrop et al. engage the skull 22, not the bone flap 16, contrary to method claim 44. Additionally, the burrs 132 are not driven laterally into the skull 22 by any mechanism, but instead rely on their normal biasing force to penetrate into the skull 22 to hold the bone flap 16 in position. Because of their normal

biasing force, there is no need for any separate implant delivery device to drive the burrs 132 laterally. Thus, it would go against the teachings of Manthrop et al. to use any sort of mechanism to laterally drive the burrs 132 into the skull 22.

Bremer's hand tool 40 does not fill in the shortcomings of Manthrop et al. Manthrop et al. and Bremer cannot be combined without requiring a substantial reconstruction of either the implant in Manthrop et al. or the hand tool of Bremer. The hand tool 40 of Bremer is adapted to clamp onto its implant 10 and then twist the implant 10 into position between the bone flap 54 and the skull 52. This twisting motion is the primary mode of operation used by the hand tool 40 in Bremer to anchor the implants 10. This hand tool 40 could not be used to mount the implants of Manthrop et al. into either the bone flap or the skull. To do so would require the implants of Manthrop et al. to be completely redesigned. This would be a direct conflict with the intended operation described in Manthrop et al. The burrs of Manthrop et al. are specifically configured to automatically penetrate into the skull without the need for any tools. Accordingly, there is no reason for one having ordinary skill in the art to attempt to use the hand tool of Bremer to mount the implants of Manthrop et al. There is no need for the hand tool. Significant modifications would be required to make this combination thereby teaching away from the combination and defeating any *prima facie* case for obviousness.

Cullen cannot be used to overcome the deficiencies in Manthrop et al. or Bremer for the same reasons described above as to why Bremer cannot be combined with Manthrop et al.. Specifically, the device of Cullen is not configured to mount the implants of either Manthrop et al. or Bremer into a bone flap or skull. The device described in Cullen relates to directly driving tacks into bone in a corpse. In Manthrop et al., the implants are mounted to the skull by burrs that rely on their normal biasing force to automatically penetrate bone. In Bremer, the implants are inserted into a gap between the bone flap and the skull and then twisted into position by a hand tool. Contrary to these mounting methods, Cullen relies on a direct driving force, like a

hammer, to drive a tack into bone. One having ordinary skill in the art would have no reason to use the device of Cullen with the implants of either Manthrop et al. or Bremer. These three references recite three very different operating principles, i.e., biasing forces, twisting forces (torque) and direct driving forces.

For these reasons, Applicants respectfully submit that claims 1 and 44 are in condition for allowance. Also, Applicants submit that dependent claims 5, 6, 10, 11, 29-31, 38-41, 46 and 47 are also allowable based on their own merits, and their dependency to allowable claims 1 and 44.

Applicants believe the application is now in condition for allowance, which allowance is respectfully solicited. Applicants believe that no additional fees are required. However, the Commissioner is authorized to charge our Deposit Account No. 08-2789 in the name of Howard & Howard Attorneys, PLLC for any additional fees or credit the account for any overpayment, including any additional fees for extensions of time that may not have already been paid.

Respectfully submitted,

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